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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,754	10/15/2001	Joseph A. Orr	5072US	2866

24247 7590 10/05/2004

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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,754	ORR ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This is a final Office action. Any changes in grounds for rejection were necessitated by the applicants' amendment to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 12, 13, 15-17, 19-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,581,595 to Murdock et al. in view of US Patent No. 5,823,184 to Gross. Murdock discloses a breath collection system for use in obtaining metabolic measurements from an individual's respiration. The system comprises a breathing apparatus 26 configured to communicate with at least a mouth of the individual and a conduit 24 including a first end coupled to a mouthpiece 26 or mask 30 and a second end configured to be coupled to an apparatus 12 for monitoring the individual's respiration (figs. 1-3). The conduit 24 is shown as being made of a flexible and accordion-like material in figure 3 (col. 3, lines 39-50), but the reference is silent as to any further details regarding the conduit or its material.

However, Gross discloses breathing circuit 10 having a flexible tube 24, 26 comprising accordion-like or corrugated, expandable, contractible, and positionable tubing material capable of assuming any bent configuration selected by a user and retaining that configuration until positioned into another bent or straight configuration (col. 5, lines 3-17; figs. 1, 4, and 8). Therefore, it would have been obvious to one of

ordinary skill in the art at the time of invention to use the flexible tubing material of Gross as the conduit in the apparatus of Murdock et al., because Murdock discloses using a flexible tube as the conduit and Gross describes tubing material for such a flexible tube. Regarding the method claims 19-21 and 23, the description of the apparatus inherently discloses the method of its use.

Regarding claims 15-17, the apparatus 12 includes a sensor 56, 58, 60 (col. 4, lines 51-53 of Murdock).

Regarding claims 19-21 and 23, the description of the apparatus of Murdock, in view of Gross, as described above, inherently teaches a method of using the device. Use of the apparatus occurs prior to sleep, at nighttime, or upon waking, indicating the patient would be in a resting position (col. 7, lines 45-65). With further regard to claim 20, the connection between the mouth of the patient and the mouthpiece 26 is substantially fluid tight to the degree that the device functions correctly in providing sufficient air to the patient and in accurate indirect calorimetry measurements.

Claims 14, 18, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murdock et al. in view of Gross, as applied to claims 1, 2, 5, 12, 13, 15-17, 19-21, and 23, and further in view of US Patent No. 5,769,702 to Hanson. Murdock, as modified fails to teach at least a section of the conduit carrying at least one elongate member. However, Hanson teaches a fluid conduit 10 for providing or removing gases comprising a malleable positioning tube 20. The tube 20 may comprise either accordion-like tubular bellows, allowing one to extend, contract, and position the tube, or it may comprise at least one malleable wire (elongate compliant member)

affixed to the positioning tube, where the wire may be bent to maintain the tube 20 in a desired shape (col. 3, lines 32-60, figs. 5-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the malleable wire in place of the accordion tube Murdock et al. in view of Gross, since Hanson discloses the functional equivalence between an accordion-like tube and a tube having a malleable wire affixed to it.

Claims 1-3, 6-13, 15-17, 19-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,042,501 to Kenny et al. in view of Gross. Kenny teaches a breath collection system usable for obtaining metabolic measurements (col. 7, lines 35-50), comprising a breathing apparatus 110 configured to communicate with at least a user's mouth and a flexible conduit 120 including a first end coupled to a mouthpiece 110 and a second end configured to be coupled to a monitoring apparatus 120 (fig. 1; col. 3, lines 35-64 of Kenny). Kenny is silent as to the details of the flexible conduit.

However, Gross discloses a tube 26 comprising a flexible tubing material that is accordion-like or corrugated, expandable, contractible, and positionable tubing and capable of assuming any bent configuration selected by a user and retaining that configuration until positioned into another bent or straight configuration (col. 5, lines 3-17; figs. 1, 4, and 8). The tube 26 is usable in a breathing circuit 10 (col. 4, lines 51-56 of Gross). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the flexible tubing material of Gross as the conduit material in

the apparatus of Kenny, since Kenny discloses using a flexible conduit, and Gross describes flexible material for such a flexible tube in a respiratory device.

Regarding claim 3, the mouthpiece 110 comprises a breathing end configured to be at least partially inserted into the mouth of the individual (fig. 1; col. 3, lines 36-38 and lines 45-49 of Kenny).

Regarding claims 6-11, the mouthpiece 110 has one-way inlet valve 111 and outlet valve 112 (col. 3, lines 37-43 of Kenny). With further regard to claim 8, the outlets facilitate the introduction of inhalation gases 113, indicating that inlet valve 111 opens upon application of negative pressure. With further regard to claim 10, the evacuation of expiratory gases 115 from breathing apparatus 110, similarly indicating that outlet valve 112 opens upon application of positive pressure.

Regarding method claims 19-21 and 23, the description of the apparatus inherently discloses the method of its use. The apparatus may be used during rest (col. 7, lines 51-55). With further regard to claim 20, the connection between the patient's mouth and the mouthpiece 110 is substantially fluid tight to the degree that the apparatus functions correctly in obtaining breath samples from the patient.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny in view of Gross, as applied to claims 1-3, 6-13, 19-21, and 23 above. Kenny, as modified, fails to show the conduit coupling section of the mouthpiece 110 oriented in a downwardly extending direction relative to the breathing end. However, the applicants have not disclosed that having the coupling section oriented in such a direction solves any stated problem or is for any particular purpose. Moreover, it appears that the

breath collection system would perform equally well with the coupling section in the orientation shown in Figure 1 of Kenny. Accordingly, the use of the downward orientation of the conduit coupling section is deemed to be a design consideration which fails to patentably distinguish over the prior art of Kenny, as modified by Gross.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny in view of Gross, as applied to claims 1-3, 6-13, 15-17, 19-21, and 23 above, and further in view of US Patent No. 5,308,792 to Mault. Kenny, as modified by Gross, fails to teach restricting respiration through the nose of a patient. However, Mault discloses an indirect calorimeter wherein a user 10 exhales into a mouthpiece 12. A nose clamp 14 may be employed in connection with the mouthpiece 12 (fig. 1, col. 3, line 65-col. 4, line 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Mault with that of Kenny, as modified by Gross, in order to ensure that all respiratory air passes through the mouthpiece, thereby ensuring a more accurate measurement.

Response to Arguments

Applicant's arguments filed 6/21/04 have been fully considered but they are not persuasive.

The applicants argue that one would have no reason to expect that the coaxial breathing circuit of Gross could be coupled to the single-lumen receiving calorimetry device of Murdock" on p. 8 of the arguments filed 6/21/04. However, the rejection based on Murdock in view of Gross relies on Gross's teaching of either the outer 26 or the outer 26 and the inner 24 tube of Gross may be made of a material that allows it to

be configured to a desired shape and substantially maintain that shape until formed to another desired shape. Gross's description shows that the outer tube 26 without the presence of the inner tube 24 would retain the same qualities, and therefore it would be suitable to use such material in conjunction with the invention of Murdock.

In response to applicant's argument that Murdock and/or Gross lack teaching or suggestion that an end of a coaxial breathing circuit may be coupled to a calorimetry device or any other type of respiratory monitor, the applicants should note that Gross does teach that the flexible tube 26 may be part of a breathing circuit that includes a respiratory monitor (col. 4, lines 51-56 of Gross). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Again, the reliance in Gross is on the tubing material taught by Gross, rather than on the entire tube itself, and that the tubing is useful in such breathing circuit such as one described by Murdock.

Regarding the applicants assertion that neither Kenny nor Gross teaches or suggest a conduit that includes a first end that is coupled to a mouthpiece and a second end that is configured to be coupled to an apparatus for monitoring an individual's respiration, the applicants should refer to the rejection presented above as to how the combined references teach such a conduit. Further, it is noted that Kenny discloses a conduit 120 that includes a first end that is coupled to a mouthpiece 110 and a second

end coupled to an apparatus 200 for monitoring an individual's respiration (fig. 1; col. 3, lines 35-57 of Kenny).

As to the applicants' argument that Kenny and Gross, taken collectively or individually fail to teach a method that includes coupling a breathing conduit to both a breathing apparatus and a sensor for monitoring an individual's respiration, the applicants are directed to the rejection presented above as to how the combined references teach such a method. Additionally, Kenny teaches coupling a breathing circuit to both a breathing apparatus 110 and a sensor 200 for monitoring an individual's respiration (fig. 1; col. 3, lines 35-57 of Kenny).

Regarding the applicants' allegation that the connection of coaxial breathing circuit of Gross to the mixing chamber of Kenny would have no value, the applicants should again note that Gross is relied upon for its teaching of tubing material and the outer tube 26 rather than on the coaxial tube itself. Furthermore, the motivation in combining the two references is the lack of disclosure in Kenny as to the composition of the conduit and the disclosure of such composition of a similar tubing in Gross.

The applicants state that the combination of Kenny and Murdock could only have been based on improper reliance upon hindsight provided by the subject matter taught and claimed in the above-reference application. It is noted that no rejection presented above or in the previous Office action relies on the combination of Kenny and Murdock.

Since the combination of Murdock and Gross and Kenny with Gross are shown above to be proper, the applicants' arguments as to the impropriety of further

combination based on these combination is moot. Therefore, the rejection of claims 1-24 stand.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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